K121804

Abbreviated 510(k) Summary

APR 19 2013

1. **Name/Address of Submitter:** **Itena Clinical**
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FRANCE

2. **Contact Person:** **Louis-Paul Marin**
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3. **Date Summary Prepared:** April 25 , 2012

4. **Devices Names:** TotalCem, DentoCem

5. **Device Classification:** II

6. **Common name:** Dental Cement

7. **Classification Product Code:** EMA

8. **Predicate Devices:**

TotalCem	**MultiLink** **K032470**	
DentoCem	**RelyX Luting Plus Cement** **K022476**	**PremaCem** **K012316**

9. **Devices Description:**

TotalCem: TotalCem is a permanent, radio-opaque dual cured (auto/photopolymerizable) self-etch and self-adhesive resin cement. The technological characteristics for this subject device are as follows:

Technological Characteristics	**Subject Device**	**MultiLink K032470**
Matrix	UDMA and BIS-GMA	UDMA and BIS-GMA
Fillers	Barium glass and Fumed Silica, TiO2	Barium glass, ytterbium trifluoride and spheroid mixedoxide
Delivery	Automix	Automix

Curing Method	Dual Cure	Dual Cure
Radiopacity (% Al)	Yes	Yes

DentoCem: DentoCem is a chemical-curing, multi-purpose, dual-cured (auto/photopolymerizable), radio opaque permanent adhesive resin cement comprised of two easy-to-mix components. The technological characteristics for this subject device are as follows:

Technological Characteristics	**Subject Device**	**PremaCem K012316**
Matrix	UDMA and BIS-GMA	UDMA and Bis-GMA
Fillers	Barium glass and Fumed Silica TiO2	Barium glass and Silica
Delivery	Automix	Automix
Curing Method	Dual Cure	Dual Cure
Radiopacity (% Al)	Yes	Yes

10. Statement of Intended Use:

Device Name: TotalCem

The device is intended for the cementation of posts, crowns, bridges, inlays and onlays.

Device Name: DentoCem

The device is intended for permanent cementation of:

- crowns and bridges, inlays, onlays, posts and cores, ceramic crowns, Maryland bridges and veneers;
- implant prosthesis;
- orthodontic attachments;
- amalgam restorations;
- veneering of alloys; and
- composite restorations.

11. Brief Description of Clinical and Non-clinical Testing: This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications". In support of this, Itena Clinical has provided information to demonstrate conformity with FDA's guidance document entitled Dental Cements – Premarket Notification, August 1998 and ISO 4049 – Dentistry – Polymer-based filling, restorative and luting materials.

Conclusion Drawn: Based on their indications for use, technological characteristics and comparison to predicate devices, the subject devices have been shown to be safe and effective for

their intended use. Further, combined with biocompatibility testing and based on a comparison of intended use and indications for use, physical properties and composition, Itena Clinical concludes that the subject devices are substantially equivalent to their respective predicates (respectively, Ivoclar Vivadent MultiLink (K032470) and 3M ESPE's predicate device, RelyXim Luting Plus Cement (K02247) and DMG, USA Permacem (K012316).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 19, 2013

Itena Clinical
C/O Mr. Louis-Paul Marin
Co-President
BCF Certification, Incorporated
500 Boul Cartier West
Laval, Canada H7V 5B7

Re: K121804
Trade/Device Name: TotalCem, DentoCem
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 27, 2013
Received: April 3, 2013

Dear Mr. Marin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use K121804

Device Name: **TotalCem**

Indication for Use: It is intended for the cementation of posts, crowns, bridges, inlays and onlays.

Device Name: **DentoCem**

Indication for Use: It is intended for permanent cementation of:

- crowns and bridges, inlays, onlays, posts and cores, ceramic crowns, Maryland bridges and veneers;
- implant prosthesis;
- orthodontic attachments;
- amalgam restorations;
- veneering of alloys; and
- composite restorations.

Concurrence of CDRH Office of Device Evaluation

Prescription Use _X_ OR Over-the-counter Use ____ (per 21CFR 801.109)

Mary S. Runner -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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